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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,759	02/26/2002	Meryl J. Squires	2972-86588	4483

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EXAMINER
JONES, DWAYNE C.

ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,759	SQUIRES, MERYL J.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on the election of 25 JUN 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
 - 4a) Of the above claim(s) 1-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 31-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-34 are pending.
2. Claims 1-30 are non-elected and withdrawn from consideration.
3. Claims 31-34 are elected and rejected.

Election/Restrictions

4. Applicant's election without traverse of Group II, corresponding to claims 25-34, in Paper No. 7 is acknowledged.
5. However, upon further consideration the Restriction requirement of February 26, 2003 should have been listed three (3) patentably distinct groups, namely Group I, for claims 1-24, drawn to a composition; Group II, for claims 25-30, drawn to a method of treating diseases; and Group III, for claims 31-34, drawn to a method of treating HIV. Since an initial election of species was made on claim 31 and applicant's representative selected the HIV for the viral disease, the claim of new Group II, which correspond to claims 25-30 are withdrawn from further consideration. It is respectfully, requested that applicant's representative address this change to the restriction requirement in your response to this office action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the phrases "other infectious diseases". In addition, the instant specification does not describe what is meant by the phrases "other infectious diseases" other than treating herpes virus and HIV. Structural identifying characteristics of the phrases "treating "other infectious diseases" are not disclosed except for those treating herpes virus and HIV. There is no evidence that there is any per se structure/function relationship between the phrases "other infectious diseases" other than those disclosed, namely treating herpes virus and HIV. The instant specification does provide an adequate written description for the phrases "other infectious diseases". Accordingly, these claims fail to comply with the written description requirement.

8. Claims 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the phrase, "combinations thereof". In addition, the instant specification does not describe

what is meant by the phrase, "combinations thereof". Structural identifying characteristics of the phrase, "combinations thereof". There is no evidence that there is any *per se* structure/function relationship between the phrase, "combinations thereof". The instant specification does provide an adequate written description for the phrase, "combinations thereof". Accordingly, these claims fail to comply with the written description requirement.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyler in view of the reference Bourbon et al. and in further view of Bryant et al.

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12. Tyler discloses that one strategy used to combat communicable diseases and infections is to stimulate the body's own immune system to resist the unwanted microorganisms, referred to as immunomodulation. Biological response modifiers or immunostimulants may affect either the cellular or humoral immune system or both. Moreover, biological response modifiers are nonspecific in character, producing general stimulation of the entire system. Tyler also teaches that biological response modifiers are more effective when used in combination with other chemotherapeutic agents, (see page 181, paragraphs 1 and 3). In addition, Tyler discloses that although the immunostimulant of Echinacea, such as Echinacea purpurea, has no direct bacterial properties, its beneficial effects arise from its ability to stimulate the immune system. In addition, increasing phagocytosis and promoting the activity of lymphocytes, which results in the increased release of tumor necrosis factor, achieve the beneficial effects of Echinacea. Echinacea has also been proposed to induce the production of interferon. Accordingly, all of these actions tend to increase the body's resistance to a bacterial activity, (see page 182, paragraphs 1-3). Tyler teaches that Echinacea was first introduced into medicine from the Indians around 1871, where it was used to treat a plethora of conditions, such as pain, wounds, and sores. Echinacea can be applied topically or orally, (see page 115, paragraph 3 and continuing on to page 116, paragraph 1). Despite the fact that Tyler is silent to employing the use of benzylalkonium halide, the prior art reference of Tyler does provide the skilled artisan with the motivation to combine biological response modifiers, namely Echinacea

purpurea, with other chemotherapeutic agents in order to increase the effectiveness of the biological response modifiers.

13. The prior art reference of Bourbon et al. teach that a benzalkonium halide, in particular benzalkonium fluoride, can also be used for the inhibition of herpes, HIV and herpes simplex, (see abstract).

14. Accordingly, it would have been obvious to one having ordinary skill in the art to utilize a formulation containing both Echinacea purpurea and benzalkonium chloride or benzalkonium fluoride, since it is well established in the art that both of these compounds can be used to treat the same ailment, specifically herpes. Moreover, the skilled artisan would have expected that the combination of these two components, Echinacea purpurea and either benzalkonium chloride or benzalkonium fluoride, would have similar activities or properties together since it is already established in the prior art are effective in treating viral infections, such as herpes. There is nothing unobvious by stating that the composition is aqueous. When the prior art references of Tyler are combined with Bourbon et al. the instant invention is rendered obvious with respect to the mode of administration of these compounds, especially since Bourbon et al. teach of compositions to treat herpes. Moreover, it would have been obvious modification to the skilled artisan to incorporate any suitable surfactants which are applicable for topical formulations, accordingly quaternary ammonium salt surfactants would have been obvious to include with topical formulations as taught by Bryant, (as listed in the prior art references of Bryant, see column 3, lines 8-38). "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same

purpose, in order to form a third composition to be used for the very same purpose. . .

.[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Obviousness-type Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 31-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,350,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to the treatment of HIV with Echinacea and benzalkonium chloride.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-

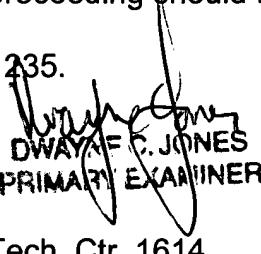
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4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE F. C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614

September 15, 2003